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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/519,642	03/06/2000	Tongtong Wang	210121.478C4	8132

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EXAMINER
BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
1631	11

DATE MAILED: 03/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/519,642	Applicant(s) Wang Et Al
	Examiner Michael Borin	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 7, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, and 4-66* is/are pending in the application.

4a) Of the above, claim(s) *1, 2, and 4-60* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *61-66* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5-7

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Status of Claims

1. Response to restriction requirements filed1/7/02 is acknowledged. Applicant elected, without traverse, Group I, claims 3, drawn to polypeptide of SEQ ID 786.

Claims 1,2,4-60 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to non-elected groups.

Claim 3 is canceled and replaced with new claims 61-66.

Abstract

2. The abstract of the disclosure is objected to because it does not reflect the invention as elected. Correction is required.

Sequence Listing

3. The Sequence Listing was approved by STIC.

Claim Rejections - 35 U.S.C. § 101/ 112-1

4. The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C.

112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

5. Claims 61-66 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a substantial and credible utility or, in the alternative, a well-established utility.

The claimed polypeptide of SEQ ID No. 786, is mentioned on pages 33,71 of specification as peptide having polypeptide sequence encoded by the polynucleotide of SEQ ID 69, is mentioned in the specification (pages 35, 130). No specific or substantial utility for this particular polypeptide is described. There is no evidence that this particular polypeptide is overexpressed in tumor lung cells and is in any way related to lung cancer development. Further, the utilities asserted in the specification are for diagnostics and treatment of lung cancer. The utility is based on the presumption that the polypeptides are specifically expressed in lung tumor. The specification addresses the polypeptides of the invention as "lung tumor proteins". A "lung tumor protein" is defined as any protein which is expressed in lung tumor cells at a level that is at least two fold greater than the level of expression in a normal tissue. The type of "a normal tissue" is not identified. Hence, the meaning of "at least two fold greater" is not clear, as well as it is no evidence that the information about the polypeptides of the invention (and polynucleotides encoding them) was obtained from a substraction libraries.

Furthermore, the claims encompass any protein comprising any fragment of the peptide SEQ ID 786; no core structure required for such peptide is identified.

Further, in regard to the variants claimed that are the result of one or more substitutions, deletions, additions, insertions, notwithstanding the specification's lack of guidance concerning combinatorial mutagenesis, at the time the invention was

made, combinatorial mutagenesis was not sufficiently developed to enable one skilled in the art to systematically make even a significant fraction of all the structural embodiments embracing the claimed subject matter. Testing and screening the infinitely vast collection embraced by the claimed subject matter for functional activity would clearly require further research to identify or reasonably confirm a "real world" context of use.

The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter. Identifying use of the claimed polypeptide would require carrying out further research. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. In addition, there is no well established utility known for polypeptide as claimed. Consequently, the claimed subject matter is not supported by substantial or well established utility.

6. Claims 61-66 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a substantial or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 62 is rejected under 35 U.S.C. 102(b) as anticipated by polypeptide of accession number AAW31603 (Database Genenseq).

The instant claims are drawn to peptides comprising at least 10 amino acid residues of polypeptide SEQ ID No. 786. The referenced polypeptide contains 21 amino acid residues of polypeptide SEQ ID No. 786. See sequence alignment attached. There are numerous references describing polypeptides comprising fragments as claimed. The references used in this rejection are exemplary.

The reference teaches polypeptide that meets the structural limitation claimed. Although the reference does not teach the functional limitation of the peptide, such a limitation would be inherent in the peptide since it meets the structural limitations of the claim. A reference which is silent about a claimed invention's feature is inherently anticipatory if the missing feature is necessarily present in that which is described in the reference. In re Oelrich, 212, USPQ 323 (CCPA 1981). Where the claimed and prior art products are identical or substantially identical in structure or

composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada,* 15USPQ2d 1655, 1658 (Fed. Cir., 1990). Threfore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Conclusion.

8. No claims are allowed

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER